

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK**

MÖLNLYCKE HEALTH CARE US, LLC,
AND BROCK USA, LLC,

Plaintiff,

v.

GREENWOOD MARKETING, LLC D/B/A
RESTORATIVE MEDICAL OR SPRY
THERAPEUTICS,

Defendant.

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Civil Action No. 7:22-cv-03719-CS

DEMAND FOR JURY TRIAL

~~PROPOSED~~ PROTECTIVE ORDER

Upon consideration of the Parties' Joint Motion for Entry of a Protective Order, is hereby
ORDERED as follows:

1. Purpose.

- a. This Order ("Protective Order") is made under Fed. R. Civ. P. 26(c). It governs any document, information, or other thing furnished by any party to any other party, and it includes documents, information, and things furnished by any nonparty who receives a subpoena in connection with this Action. The information protected includes, but is not limited to, the following: answers to interrogatories; answers to requests for admission; responses to requests for production of documents; deposition transcripts and videotapes; deposition exhibits; and other writings or things produced, given or filed in this Action that are designated by a party as "Confidential Material" or "Confidential Material—Outside Attorney Eyes Only" according to the terms of this Protective Order, as well as to any copies, excerpts, abstracts, analyses, summaries, descriptions, or other forms of recorded information containing, reflecting, or

disclosing such material. The designation of a document, material, or information (whether written, graphic, or electronic) as being subject to the terms and conditions of this Protective Order is intended solely to facilitate prompt discovery and the preparation for trial of this Action.

2. Scope.

- a. This Protective Order shall govern all hardcopy and electronic materials, the information contained therein, and all other information including all copies, excerpts, summaries, or compilations thereof, whether revealed in a document, deposition, other testimony, discovery response, or otherwise, that any party to this proceeding (the “Producing Party” or “Designating Party”) produces to any other party (the “Receiving Party”) and that the Producing Party designates as confidential under this Protective Order.
- b. This Protective Order is binding upon all Parties and their counsel in this proceeding, upon all signatories to Exhibit A, and upon (as applicable) their respective corporate parents, subsidiaries, and affiliates, including their successors, and their respective attorneys, principals, experts, consultants, representatives, directors, officers, employees, and others as set forth in this Protective Order.
- c. If additional parties are added other than parents, subsidiaries, or affiliates of current parties to this litigation, their ability to receive a document protected by this Protective Order will be subject to their being bound, by agreement or Court Order, to this Protective Order.
- d. Third Parties who are obligated to produce Confidential Material or Confidential Material—Outside Attorney Eyes Only in this Action and who so elect, may avail

themselves of and agree to be bound by the terms and conditions of this Protective Order, and thereby become a Producing Party for purposes of this Protective Order.

- i. The existence of this Protective Order must be disclosed to any Third Parties producing documents, tangible things, or testimony in this Action who may reasonably be expected to desire confidential treatment for such documents, tangible things, or testimony.
- e. The entry of this Protective Order does not preclude any Party from seeking further order of this Court, including modification of this Order, or from objecting to discovery that the Party believes to be improper.
- f. Nothing in this Protective Order shall be construed as an admission or concession by any Party that designated Confidential Material, or any Document or Information derived from Confidential Material, constitutes material, relevant, or admissible evidence in this Action.
 - i. Producing or receiving Confidential Material or otherwise complying with the terms of this Protective Order will not (a) operate as an admission by any party that any particular Confidential Material contains or reflects trade secrets or any other type of confidential or proprietary information; (b) prejudice the rights of a party to object to the production of information or material that the party does not consider to be within the scope of discovery; (c) prejudice the rights of a party to seek a determination by the presiding judge that particular materials be produced; (d) prejudice the rights of a party to apply to the presiding judge for further protective orders; or (e) prevent the parties from agreeing in writing to alter or waive the provisions or protections provided for in this Protective Order

with respect to any particular information or material.

3. Definitions. In this Order, the terms set forth below shall have the following meanings:

- a. “Proceeding” or “Action” means the above-captioned action.
- b. “Court” means the Honorable Judge currently assigned to this proceeding or any other judge to which this proceeding may be assigned, including Court staff participating in such proceedings.
- c. “Document” or “Documents” shall have the meaning set out in Federal Rule of Civil Procedure 34(a), Federal Rule of Evidence 1001, and, for purposes of this Order, shall include electronically stored information.
- d. “Testimony” means all depositions, declarations or other pre-trial testimony taken or used in this Proceeding.
- e. “Information” means the content of Documents or Testimony, as well as any matter derived therefrom or based thereon.
- f. “Confidential Material” or “Confidential Discovery Material” means any Document (electronic or hard copy), Testimony, or Information that a Designating Party reasonably believes to be entitled to confidential treatment under applicable laws and that the Party designates as such in accordance with the provisions of this Order. “Confidential Material” includes, but is not limited to:
 - i. Personal identifying information, financial information, medical/insurance information, and, with respect to any Party, any other information that the Designating Party reasonably believes to be subject to protection from disclosure by a natural person’s right of privacy under applicable privacy laws or regulations;

- ii. Trade secrets (as defined in the Uniform Trade Secrets Act) or commercial information that is not publicly known and is of technical or commercial advantage to its possessor, in accordance with Rule 26(c)(7), or other information required by law or agreement to be kept confidential, including: documents containing or constituting research and development, marketing or training, confidential business, commercial, or proprietary information, financial information or data, technical information, manufacturing processes, product specifications, engineering information and testing, distribution processes, or sensitive health or medical information; or other proprietary or confidential business information of commercial value and reasonably believed to be subject to protection from disclosure under applicable statutes, laws, or regulations; and
- iii. All material, data, and information obtained, derived, or generated from “Confidential Material,” to the extent the same are not publicly available (information is not deemed to be publicly available merely because it is in possession of an entity other than the entity that believes the information to be confidential, such as information obtained or retained improperly) or otherwise subject to the exclusions herein.
- iv. Specifically excluded from the definition of “Confidential Material” are:
 - 1. Any Documents, Testimony, or Information that have been designated as “not confidential” by order of any court;
 - 2. Any Documents, Testimony, or Information obtained by any person or entity through procedures established under the Freedom of Information

Act or other public records request.

- g. The phrase “Confidential Material—Outside Attorney Eyes Only” refers to Confidential Material that the Designating Party reasonably, and in good faith, believes to contain highly confidential information, the disclosure of which to the Party’s competitors would cause the Designating Party serious competitive and commercial harm. This includes any information that the Producing Party deems especially sensitive, which may include, but is not limited to, confidential research and development, product design, financial, technical, marketing, or any other sensitive trade secret information. As used in this Order, and unless otherwise specified, “Confidential Material” shall encompass “Confidential Material—Outside Attorney Eyes Only.”
 - i. “Confidential Material” and “Confidential Material—Outside Attorney Eyes Only” do not include, and this Protective Order does not apply to, information that is already in the knowledge or possession of the party to whom disclosure is made unless that party is already bound by agreement not to disclose such information, or information that has been disclosed to the public or third persons in a manner making such information no longer confidential.
 - ii. In so marking documents, however, the Parties and their counsel expressly agree that they will only designate as “Confidential” or “Confidential – Outside Attorney Eyes Only” documents actually meeting the definitions above, and will not engage in wholesale marking of documents produced or exchanged in discovery as “Confidential” or “Confidential – Outside Attorney Eyes Only,” whether as a means of inhibiting, burdening, or encumbering the other Parties’ ability to

present a claim or defense in this action, or otherwise.

- h. “Designating Party” means the Party or non-party that designates Documents, Testimony, or Information as Confidential Material.
- i. “Disclose,” “Disclosed,” or “Disclosure” means to reveal, divulge, give, or make available Documents, Testimony, or any part thereof, or any Information contained therein.

4. Designations of Confidential Material.

a. Designation of Documents.

- i. Documents Produced in TIFF format. With respect to any Document produced in TIFF format, a Designating Party may designate the Document as Confidential Material or Confidential Material—Outside Attorney Eyes Only by placing a stamp or marking on each page of the Document stating the following: **CONFIDENTIAL, SUBJECT TO PROTECTIVE ORDER, PRODUCED BY [PARTY NAME] IN [NAME OF LITIGATION]** or **CONFIDENTIAL—ATTORNEY EYES ONLY, SUBJECT TO PROTECTIVE ORDER, PRODUCED BY [PARTY NAME] IN [NAME OF LITIGATION]**. Such markings shall not obscure, alter, or interfere with the legibility of the original document.

- 1. All copies, duplicates, extracts, summaries, or descriptions (hereinafter referred to collectively as “copies”) of Confidential Material produced in TIFF format shall be marked with the same confidential stamp or marking as contained on the original, unless the original confidential stamp or marking already appears on the copies.

ii. Documents Produced in Native Format. With respect to any Document produced in native format (“Native-Format Document”), a Designating Party may designate the Document as Confidential Material or Confidential Material—Outside Attorney Eyes Only by renaming the Document to include, at the end of the file name and prior to the file extension, the following language: **CONFIDENTIAL** or **CONFIDENTIAL—ATTORNEY EYES ONLY**.

1. Native-Format Documents that have been designated as Confidential may have to be copied or duplicated for use in a litigation-support review application. Any such copy or duplicate shall retain the full file name as originally produced.
2. For use outside a litigation-support review application, Receiving Parties may make native-format copies or duplicates of a Native-Format Document that have been designated as Confidential solely (a) for use with experts or consultants who are retained in this Action and who are Qualified Persons as defined below or (b) for use as deposition or trial exhibits. Any such copy or duplicate shall retain the full file name as originally produced to the extent practicable.
3. All other copies or duplicates of Native-Format Documents (*e.g.*, TIFF-image, PDF, hardcopy) and all extracts, summaries, or descriptions of Native-Format Documents shall contain a stamp or marking on each page of the Document stating the following: **CONFIDENTIAL, SUBJECT TO PROTECTIVE ORDER, PRODUCED BY [PARTY**

**NAME] IN [NAME OF LITIGATION] or CONFIDENTIAL—
ATTORNEY EYES ONLY, SUBJECT TO PROTECTIVE
ORDER, PRODUCED BY [PARTY NAME] IN [NAME OF
LITIGATION].** Such markings shall not obscure, alter, or interfere
with the legibility of the original document.

b. Designation of Deposition Transcripts.

- i. During depositions, Confidential Material may be used or marked as exhibits, but shall remain subject to this Order and may not be shown to the witness unless such witness is a Qualified Person as described below.
- ii. If deposition Testimony or exhibits contain or refer to Confidential Material, or if they contain or refer to Documents, Testimony, or Information to be designated as Confidential Material, the Designating Party, by and through counsel, shall either:
 1. On the record at the deposition, designate the Testimony or exhibit(s) as Confidential Material or, as applicable, identify already-designated Confidential Material; or
 2. No later than thirty (30) days after receiving a copy of the deposition transcript, inform the deposing counsel and counsel for other Parties that specific portions of the Testimony or specific exhibit(s) constitute Confidential Material; during the thirty-day period, the entire deposition testimony, transcript, and exhibits shall be treated as Confidential Material under this Order.
- iii. When a Party designates testimony as Confidential Material during the

deposition, counsel for that Party may exclude from the deposition all persons who are not Qualified Persons under this Order.

- iv. When portions of a deposition transcript or its exhibits are designated for protection, the transcript or its exhibits are designated for protection, the transcript or exhibit pages containing Confidential Material shall be separately bound by the court reporter, who must affix to the top of each page the legend **“CONFIDENTIAL, SUBJECT TO PROTECTIVE ORDER IN [NAME OF LITIGATION]”** or **“CONFIDENTIAL—ATTORNEY EYES ONLY, SUBJECT TO PROTECTIVE ORDER IN [NAME OF LITIGATION].”**
 - v. It is the responsibility of counsel for each party to maintain materials designated “Confidential Material” or “Confidential Material—Outside Attorney Eyes Only” in a secure manner and appropriately identified so as to allow access to such information only to such persons and under such terms as is permitted under this Protective Order.
- c. Written Pleadings, Motion Papers, and Discovery Materials. A party may designate as Confidential Material portions of interrogatories and interrogatory answers, responses to requests for admissions and the requests themselves, requests for production of documents and things and responses to such requests, pleadings, motions, affidavits, and briefs that quote, summarize, or contain Confidential Material. To the extent feasible, such Confidential Material shall be prepared in such a manner that it is bound separately from material not entitled to protection.
- d. Designation of Other Confidential Material. With respect to Confidential Material produced in some form other than as described above, including, without limitation,

compact discs or DVDs or other tangible items, the Designating Party must affix in a prominent place on the exterior of the container or containers in which the Information or item is stored the legend “**CONFIDENTIAL, SUBJECT TO PROTECTIVE ORDER, PRODUCED BY [PARTY NAME] IN [NAME OF LITIGATION],**” or “**CONFIDENTIAL—ATTORNEY EYES ONLY, PRODUCED BY [PARTY NAME] IN [NAME OF LITIGATION].**” If only portions of the Information or item warrant protection, the Designating Party, to the extent practicable, shall identify the portions that constitute Confidential Material.

- e. With respect to Documents or Information produced or disclosed by a non-party, either the non-party (if they agree to be bound by this Order) or a Party may designate the Documents or Information as Confidential Material pursuant to this Order. A Party so designating material produced by a non-Party shall notify all other Parties within 30 days of receipt of such Document or Information that the same or portions thereof constitute or contain Confidential Material. Until the expiration of 30 days, such Document or Information produced or disclosed by any such non-party shall be treated as Confidential Material under this Order.

5. Required Treatment of Confidential Material.

- a. Except as specifically provided in this Order, counsel shall keep all Confidential Material disclosed or produced to them within their exclusive possession and control, shall take all necessary and prudent measures to maintain the confidentiality of such materials and information, and shall not permit unauthorized dissemination of such materials to anyone.
- b. Confidential Material shall not be disclosed in any way to anyone for any purpose other

than as required for litigation purposes in this Action, including but not limited to preparation of trial in this Action.

- i. Nothing in this Order shall preclude a Party from introducing into evidence at trial or evidentiary hearing any Confidential Material that is admissible under applicable law. The Parties shall meet and confer regarding the procedures for use of Confidential Material at trial or any evidentiary hearing and shall move the Court for entry of an appropriate order. At trial or evidentiary hearings, the Court may take such other measures or enter separate orders, as the Court deems appropriate or upon request by any Party, to protect the claimed Confidential Material sought to be introduced or admitted.
- c. Access to and disclosure of Confidential Material shall be limited to those persons designated as Qualified Persons, below. Any Qualified Person who examines any Confidential Material shall not disseminate orally, or by any other means, any protected information other than as permitted by this Order.
- d. Confidential Material shall not be used for any business, competitive or other non-litigation purpose without the express written consent of counsel for the Designating Party or by order of the Court.
 - i. Nothing in this Protective Order shall limit any Designating Party's use of its own documents or shall prevent any Designating Party from disclosing its own Confidential Material to any person for any purpose.
 - ii. Disclosures described in the above sub-paragraph shall not affect any confidential designation made pursuant to the terms of this Protective Order so long as the disclosure is made in a manner that is reasonably calculated to

maintain the confidentiality of the designated Information, Testimony, and/or Document.

- e. To avoid security risks inherent in certain current technologies and to facilitate compliance with the terms of this Order, and unless otherwise ordered or agreed upon in writing by the Designating Party whose Confidential Material is at issue, all Qualified Persons with access to Confidential Material (i) shall not permit or enable unauthorized dissemination of Confidential Material to anyone; (ii) shall take all necessary and prudent measures to preserve the security of Confidential Material, including measures to minimize risks of unauthorized hacking of systems on which Confidential Material is stored or through which it is transmitted; and (iii) shall physically store, maintain, and transmit Confidential Material solely within the United States.

6. Qualified Persons with Respect to Confidential Material. Confidential Material (as distinct from Confidential Material—Outside Attorney Eyes Only) may be disclosed only to the following persons (referred to as “Qualified Persons” throughout this Order):

- a. Defendant (including, if applicable, partners, directors, officers, and employees of defendant), its inside and outside counsel, as applicable, and the Plaintiffs (including, if applicable, partners, directors, officers, and employees of plaintiffs), their inside and outside counsel, as applicable;
- b. With respect to inside and outside counsel encompassed by the preceding paragraph, such persons include the attorneys’ partners, employees, and agents (*e.g.*, paralegals, assistants, secretaries, outside copy services, organizations (“litigation-support services”) involved in organizing, filing, coding, converting, storing, or retrieving data

- or designing programs for handling data connected with this Action, including the performance of such duties in relation to a computerized litigation support system, and stenographers);
- c. Experts, consultants, and case-specific professionals (“Consultants”) whose assistance is necessary to assist counsel in the preparation of this Proceeding, whether or not the Consultant is designated as an expert and retained to testify, with the following qualifications:
- i. Disclosure shall not be made to any consultant who, as described in Paragraph 9, is employed by or a consultant to a competitor of the Designating Party;
 - ii. Disclosure shall not be made to any consultant if counsel for the Party retaining that consultant has actual knowledge that the consultant has been found to have violated the terms of a protective order in any litigation or legal proceeding; and
 - iii. Any consultant, expert or professional to whom disclosure of Confidential Material is authorized must be informed of this Protective Order and must sign a copy of Exhibit A.
- d. A deponent or a witness at a deposition or pre-trial hearing, provided there is a reasonable basis to believe that the witness will give relevant testimony regarding the Confidential Material or that disclosure of Confidential Material is necessary to prepare the witness for the testimony.
- i. If a Party wishes to disclose Confidential Material to such a deponent or witness before or during a deposition or pre-trial hearing, the deponent or witness must be informed of this Protective Order and either sign a copy of Exhibit A or consent under oath on the record to abide by its provisions.

- ii. The Parties agree that this provision does not preclude the Designating Party from objecting to or moving to preclude disclosure to any deponent or witness, or to seek amendment of this provision in the future, if it believes it has a good faith basis for such objection or motion;
- e. A person identified in the Confidential Material as an author, source, addressee, or recipient of the communication, or who already has a copy of the Confidential Material;
- f. Any mediators or arbitrators selected to assist in resolution of this Action, and their personnel who are actively engaged in assisting them;
- g. The Court or any Court personnel, including any court reporters; and
- h. Any person mutually agreed upon among the Parties, provided that such person has been informed of this Protective Order and has signed a copy of Exhibit A.
- i. Absent mutual agreement among the Parties, under no-circumstances will “Confidential Material – Outside Attorney Eyes Only” be provided to in-house counsel for any party.

7. Qualified Persons with Respect to Confidential Material—Outside Attorney Eyes Only. Confidential Material—Outside Attorney Eyes Only may be disclosed only to the following Qualified Persons:

- a. Outside attorneys of record in this Action, and their paralegals or their other employees or agents (including litigation-support services and any other persons covered by Section 6(b)) who require access to Confidential Material—Outside Attorney Eyes Only for the purpose of litigation of this Action;
- b. Consultants who are Qualified Persons described in Paragraph 6(c) and its subparagraphs above;

- c. A person identified in the Confidential Material—Outside Attorney Eyes Only as an author, source, addressee, or recipient of the communication, or who already has a copy of the Confidential Material—Outside Attorney Eyes Only;
- d. Any mediators or arbitrators selected to assist in resolution of this Action, and their personnel who are actively engaged in assisting them;
- e. The Court or any Court personnel, including any court reporters; and
- f. Any person mutually agreed upon among the Parties, provided that such person has been informed of this Protective Order and has signed a copy of the Confidentiality Agreement attached as Exhibit A.

8. Further Requirements with Respect to Qualified Persons.

- a. Before being given access to any Confidential Material, one authorized representative of each outside vendor, consultant, expert, or any other person or entity assisting outside counsel shall be advised of the terms of this Order, shall be given a copy of this Order, shall agree in writing to be bound by the terms of this Order by signing a copy of Exhibit A, and shall consent to the exercise of personal jurisdiction by this Court in any proceeding(s) to determine if the signatory violated this Order. Counsel for each Party shall maintain a list of all such signatories, which list shall be available for inspection by the Court. For the sake of clarity, the Court, employees and staff of the Court, counsel of record, the employees of counsel of record or their law firms, the direct employees of the parties, and witnesses to whom Confidential Material is disclosed pursuant to Paragraph 6(d) need not sign Exhibit A.
 - i. Further, prior to disclosing Confidential Material to a receiving party's proposed expert, consultant, or the expert or consultant's employees, agents, or

other assistants, the receiving party must provide to the Producing Party a signed copy of Exhibit A; the resume or curriculum vitae of the proposed expert or consultant; the expert's or consultant's business affiliation; a list of cases in which the witness has testified as an expert at trial or by deposition within the preceding five (5) years; an identification of any patents or patent applications in which the expert or consultant is identified as an inventor or applicant, is involved in prosecuting or maintaining, or has any pecuniary interest; and any current and past consulting relationships in the industry.

- ii. The Producing Party will thereafter have ten (10) days from receipt of the Confidentiality Agreement to object to any proposed individual. The objection must be made for good cause and in writing, stating with particularity the reasons for the objection. Failure to object within ten (10) days constitutes approval.
 - iii. If the parties are unable to resolve any objection, the receiving party may apply to the Court to resolve the matter. There will be no disclosure to any proposed individual during the ten (10) day objection period, unless that period is waived by the Producing Party, or if any objection is made, until the parties have resolved the objection, or the presiding judge has ruled upon any resultant motion.
- b. The witness who is a Qualified Person pursuant to Paragraph 6(d) may be shown Confidential Material during his or her testimony, but shall not be given a copy of the Confidential Material to keep. Before reviewing his or her transcribed testimony containing the Confidential Material for purposes of completing the errata sheet, such

witness shall sign a copy of Exhibit A and shall consent to the exercise of personal jurisdiction by this Court in any proceeding(s) to determine if the signatory violated this Order.

- i. In the event of disclosure under this paragraph, only the reporter, the person, his or her counsel, the presiding judge, and persons to whom disclosure may be made and who are bound by this Protective Order, may be present during the disclosure or discussion of Confidential Material. Disclosure of material pursuant to this paragraph does not constitute a waiver of the confidential status of the material so disclosed.
 - c. Any Confidential Material distributed or disclosed to a Qualified Person who has signed Exhibit A shall be returned to the Party's counsel who provided it to the Qualified Person or shall be destroyed at the completion of the Qualified Person's consultation or representation in this case. Upon the request of the Designating Party or the Court, each such Qualified Person shall execute an affidavit stating that all such Confidential Material and copies thereof have been returned or destroyed as required.
 - d. The Court shall retain jurisdiction over any person or organization authorized, as set forth above, to receive Confidential Material as necessary to enforce the provisions of this Order.
- 9. Non-Disclosure to Competitors.** Notwithstanding the foregoing, without express written consent or court order, in no event shall any disclosure of a Party's Confidential Material or Confidential Material—Outside Attorney Eyes Only be made to any known Competitor of that Party, the Receiving Party's in-house counsel, or to any person who, upon reasonable and good faith inquiry, could be determined to be a current employee thereof

or consultant doing research for a competitor of a Designating Party irrespective of whether such consultant or person is retained as an expert in this Action. This provision does not apply to outside counsel of record in this Proceeding, or to the Defendant's designated in-house counsel only to the extent they are specifically qualified to receive certain information under Sections 6 through 8 of this Protective Order. A "Competitor," in the context of this Proceeding, shall mean any manufacturer of, or manufacturer involved in the sale of, medical devices or current employee of such entity, including a consultant doing research for a Competitor of the Designating Party.

- a. In the case of an expert or consultant, the expert or consultant is best suited to know whether he or she is a Competitor of a Party, or if he or she is a current employee of or consultant doing research for a Competitor of the Designating Party. Thus, a Party seeking to use another Party's Confidential Material shall be required by the Protective Order to make a full inquiry of the expert or consultant and to obtain a declaration from him or her on these topics before any information is shared with the expert or consultant. An expert who has signed the Protective Order's Exhibit A and been disclosed under Sections 6 through 8 is deemed to have confirmed that to the best of their knowledge they are not a Competitor of a Party as defined by the Protective Order. Nothing in this Order shall limit a Party's ability to oppose a disclosed expert on the ground that he or she is a Competitor.
- b. To this end, the expert or consultant shall provide written certification whether he or she is a Competitor of a Party, whether he or she is currently employed by a Competitor, and whether he or she is contracted with a Competitor and doing research for such Competitor.

- c. No Party shall disclose another Party's Confidential Material to any expert or consultant who certifies that he or she is a Competitor of a Party, is currently employed by a Competitor, or is contracted with a Competitor and doing research for such Competitor.
- d. A Party using another Party's Confidential Material shall maintain each respective expert's or consultant's certification under this paragraph for the duration of the litigation so they may be submitted to the Court for *in camera* review in the event of a dispute between the Parties.

10. Challenges to Designations and Redactions.

- a. The Designating Party bears the burden of establishing confidentiality.
- b. Nothing in this Order shall constitute a waiver of any Party's right to object to the designation or non-designation of Documents, Testimony, or Information as Confidential Material or Confidential Material—Outside Attorney Eyes Only.
- c. If a Party contends that any Document, Testimony, or Information has been erroneously or improperly designated as Confidential Material or as Confidential Material—Outside Attorney Eyes Only, or has been improperly redacted, the material at issue shall be treated as confidential and/or remain redacted under the terms of this Order until either:
 - i. the Parties reach a written agreement; or
 - ii. this Court issues an order determining that the material is not confidential and shall not be given confidential treatment, and/or that the material was improperly redacted and shall not be redacted.
- d. In the event that counsel for a Party receiving Confidential Material in discovery

- objects to such designation or redactions, said counsel shall advise counsel for the Designating Party, in writing, of such objections, the specific Confidential Material (identified by Bates number, if possible) and/or redactions to which each objection pertains, and the specific reasons and support for such objections (the “Designation Objections”). A Receiving Party may challenge a Producing Party’s designations and/or redactions at any time.
- e. Counsel for the Designating Party shall have 10 business days from receipt of the written Designation Objections to respond in writing as to whether the designations and/or redactions will be maintained or withdrawn.
 - f. If the Designating Party does not voluntarily de-designate the challenged Confidential Material or rescind the redactions at issue, the Parties shall meet and confer in good faith, by phone or in-person, to discuss the Designation Objections and attempt to resolve the dispute within five (5) business days thereafter.
 - g. If, after meeting and conferring in good faith, the Parties are unable to resolve the dispute regarding the Designation Objections, the Party challenging the designations and/or redactions may file a motion with the Court at any time thereafter seeking an order to de-designate (*i.e.*, to rule to be not confidential) the Confidential Material and/or remove the redactions subject to the Designation Objections (the “Designation Motion”).
 - h. Notwithstanding the foregoing timeframes, in the event that Court-ordered deadlines (such as the close of discovery, scheduled depositions, and/or trial readiness dates) require an accelerated disposition of any such Designation Challenge to redactions, the Parties shall, on a more expedited basis, meet and confer and bring their dispute to the

Court immediately thereafter if, after such good faith efforts, the issue remains unresolved.

- i. Pending a resolution of the Designation Motion by the Court, the Designating Party is presumed to have designated the Confidential Material and/or inserted the redactions in good faith, and all existing designations and/or redactions challenged in such Designation Motion shall remain in place.
- ii. The Designating Party shall have the burden of establishing the applicability of its “confidential” designation.

11. Use of Confidential Material in Court Prior to Trial. The Parties will use the following procedure, absent further Court Order, for disclosing Confidential Material to the Court prior to trial.

- a. Confidential Material is not to be filed with the Court except when required in connection with motions or other submissions to the Court in this Action.
- b. The Party seeking to file Confidential Material or a document reflecting or including Confidential Material in support of a motion or other submission to the Court in this Action may (but shall not be required to) first notify the Designating Party of its intent and seek agreement to de-designate such material.
- c. Absent any such agreement, if Confidential Material or a document reflecting or including Confidential Material is submitted to or otherwise disclosed to the Court in connection with a motion or other submission to the Court in this Action, such Confidential Material shall be separately filed under seal with the clerk of the Court in an envelope marked: “CONFIDENTIAL – FILED UNDER SEAL PURSUANT TO PROTECTIVE ORDER AND WITHOUT ANY FURTHER SEALING ORDER

REQUIRED” or “CONFIDENTIAL—ATTORNEY EYES ONLY – FILED UNDER SEAL PURSUANT TO PROTECTIVE ORDER AND WITHOUT ANY FURTHER SEALING ORDER REQUIRED.” On the outside of the envelope, a copy of the caption page of the applicable pleading shall be attached. No Confidential Material, nor any part thereof, shall be included in such caption page nor otherwise be revealed on the outside of the envelope.

- i. When this Action has concluded, the Clerk of Court may return to counsel for the Designating Party, or may destroy, any Confidential Material filed under seal pursuant to the provisions of this Order.
- d. Information designated as “Confidential Material” or “Confidential Material—Outside Attorney Eyes Only” may only be used for purposes of preparation, analysis, settlement negotiations, trial, and/or appeal of this Action. Information designated “Confidential Material” or “Confidential Material—Outside Attorney Eyes Only” may not be used under any circumstances for any other purpose, except upon Court order or pursuant to lawful subpoena, as provided in paragraph 13 herein.

12. Redactions.

- a. To protect against unauthorized disclosure of Confidential Material, and to comply with all applicable state and federal laws and regulations, the Producing Party may redact from produced documents, materials and other things, the following items, or any other item(s) protected from disclosure by statute or decisional authority or agreed upon by the Parties or ordered by the Court:
 - i. The names, street addresses, Social Security numbers, tax identification numbers, and other personal identifying information of patients, health care

providers, and individuals in clinical studies or adverse event reports. Other general identifying information, however, such as patient or health provider numbers, shall not be redacted unless required by state or federal law.

- ii. The Social Security numbers, tax identification numbers and other personal identifying information of employees in any records.
- b. The Parties reserve the right to redact non-public information that is nonresponsive (including but not limited to proprietary financial material and products unrelated to this litigation).
- c. Pursuant to 21 C.F.R. §§ 314.430(e) & (f) and 20.63(f), the names of any person or persons reporting adverse experiences of patients and the names of any patients that are not redacted shall be treated as Confidential, regardless of whether the document containing such names is designated as Confidential Material.
- d. Notwithstanding any of the foregoing provisions, nothing contained in this Protective Order shall be construed as a waiver of a Party's ability to challenge such redactions pursuant to the procedures set forth in Section 11 herein. The burden as to the propriety of any redaction remains on the Designating Party at all times.

13. Subpoena by Other Courts or by Agencies.

- a. If another court or an administrative agency requests, subpoenas, or orders the disclosure of Confidential Material from a Party that has obtained such material under the terms of this Order, the Party so requested, subpoenaed, or ordered shall, if not prohibited under applicable law, notify the Designating Party by electronic mail transmission, express mail, or overnight delivery to counsel of record for the Designating Party not later than ten (10) days prior to producing or disclosing any

Confidential Material, and shall furnish such counsel with a copy of the requests, subpoena, or order. The recipient of the request, subpoena, or order shall not disclose any Confidential Material pursuant to the request, subpoena, or order prior to the date specified for production on the request, subpoena, or order.

- b. Upon receipt of this notice, the Designating Party may, in its sole discretion and at its own cost, move to quash or limit the request, subpoena, or order, otherwise oppose the disclosure of the Confidential Material, or seek to obtain confidential treatment of such Confidential Material, to the fullest extent available under law, by the person or entity issuing the request, subpoena, or order. The Party who received the request, subpoena, or order shall not oppose or otherwise interfere with the Designating Party's effort to quash or limit the request, subpoena, or order.

14. Disposition of Confidential Material.

- a. Upon the request of any Party after the conclusion of this Action (including, without limitation, any appeals and after the time for filing all appellate proceedings has passed), each Party so requested shall return all Confidential Material to counsel for the Party that produced it, shall destroy it, or otherwise shall comply with an applicable order of the Court, subject to the exception described in this Protective Order.
- b. The return or destruction of Confidential Material under this paragraph shall include, without limitation, all copies, and duplicates thereof, including copies on any litigation-support document review application, which shall not be considered work product for purposes of this Paragraph 14.
- c. The Parties shall certify, within 60 days of receipt of a written request for certification, that all Confidential Material required to be returned or destroyed has been so returned

or destroyed.

- d. As an exception to the above requirements, and unless otherwise ordered by the Court, in-house and outside counsel may retain: (a) copies of pleadings or other papers that have been filed with the Court and that are Confidential Material or that reflect, reference, or contain Confidential Material; (b) their work product, including emails containing work product; and (c) official transcripts and exhibits thereto. The terms and provisions of this Order shall continue to apply to any such materials retained by counsel. Copies of Confidential Material on a Party's litigation-support systems shall not be considered work product and shall be disposed of in a manner consistent with this Order. Confidential Material that is not reasonably accessible because it is stored on media (*e.g.*, backup storage media) is sequestered and thus need not be returned or destroyed. Should such data be retrieved by the Receiving Party, that Party must promptly take steps to destroy the restored Confidential Material.

15. Order Survives Termination of Action. After the termination of this Action by entry of a final judgment, stipulation, or order of dismissal, the provisions of this Order shall continue to be binding. This Order is, and shall be deemed to be, an enforceable agreement between the Parties, their agents, and their attorneys. The Parties agree that the terms of this Order shall be interpreted and enforced by this Court.

16. No Waiver of Any Privilege Upon Unintentional Production of Privileged Information.

- a. The Parties have agreed that, in discovery in this Action, they do not intend to disclose information subject to a claim of attorney-client privilege or attorney work product protection.

- i. This Order does not affect or constitute a waiver of any Party's right to withhold

or redact information protected from disclosure by the attorney-client privilege, physician-patient privilege, work product doctrine, or any other applicable privilege, protection, law, or regulation.

- ii. Pursuant to Federal Rule of Evidence 502(d) and Federal Rule of Civil Procedure 26(b)(5)(B), the inadvertent production of privileged or work product material that the Disclosing Party thereafter claims should not have been produced or disclosed based on privilege or work product protections (“Disclosed Privileged Information”) is not necessarily a waiver in the pending case or in any other federal or state proceeding. The inadvertent production of privileged or work product discovery material shall not itself constitute a waiver for any purpose unless that production forfeits the protections under Federal Rule of Evidence 502.
- iii. The Parties shall exchange privilege logs by 30 days before the fact discovery cutoff for all Document productions made by 90 days before the fact discovery cutoff. The Parties further agree that for any Document productions served thereafter, the Producing Party shall provide a privilege log within 30 days after serving the corresponding Document production. The Parties agree that Information or Documents withheld on the basis of work product prepared by or at the direction of counsel after the institution of this Action and privileged communications after the institution of this Action need not be identified on any privilege log. With respect to partially privileged Documents produced in redacted form, such that the sender and recipients of such Documents are disclosed on the Document as produced, a Party may identify such Documents

on a privilege log by providing an Excel-format chart that states, for each such Document, the beginning Bates number and the basis of the redaction.

- b. Attorney's Ethical Responsibilities. Nothing in this Order overrides any attorney's ethical responsibilities to refrain from examining or disclosing materials that the attorney knows or reasonably should know to be privileged and to inform the Disclosing Party that such materials have been produced. Any Party receiving materials that, on their face, appear to be covered by a privilege, shall not copy, distribute, or otherwise use in any manner such materials and shall provide prompt notice of the disclosure to the Producing Party to afford the Producing Party the opportunity to request return of the materials, in accordance with the terms of this paragraph. If a Disclosing Party notifies the Receiving Party of inadvertently Disclosed Privileged Information, the Receiving Party shall, within ten (10) court days either: (i) return or destroy (or in the case of electronically stored information, delete) all copies of such Disclosed Privileged Information (including all notes or other work product of the Receiving Party reflecting the contents of the Disclosed Privileged Information) within their possession, custody, or control—including all copies in the possession of experts, consultants, or others to whom the Disclosed Privileged Information was provided, (ii) provide a certification of counsel that all such Disclosed Privileged Information has been returned or destroyed. From the moment a Disclosing Party provides notice of production of inadvertently Disclosed Privileged Information, a Receiving Party shall not copy, distribute, or otherwise use in any manner the disputed Documents or Information, and shall instruct all persons to whom the Receiving Party has disseminated a copy of the Documents or Information that the Documents or

Information are subject to this Order and may not be copied, distributed, or otherwise used pending a motion and further notice from the Court. For purposes of this Order, Disclosed Privileged Information that has been stored by the Receiving Party on a source of electronically stored information that is not reasonably accessible, such as backup storage media, is sequestered and thus need not be returned or destroyed. If such data is retrieved, the Receiving Party must promptly take steps to delete the restored Disclosed Privileged Information.

- c. The Receiving Party may also contest any claim of attorney-client privilege or work product protection. If the Receiving Party contests the claim of attorney-client privilege or work product protection, the Receiving Party may—within five (5) business days of receipt of the notice of inadvertent disclosure—move the Court for an Order compelling production of the Disclosed Privileged Information (“Disclosure Motion”). Such a Disclosure Motion shall be filed or lodged conditionally under seal and shall not assert as a ground for entering such an Order the fact or circumstances of the production of Disclosed Privileged Information. Pending resolution of the Disclosure Motion, the Receiving Party must not use the challenged Disclosed Privileged Information in any way or disclose it to any person other than those required by law to be served with a copy of the sealed Disclosure Motion. On any such Disclosure Motion, the Disclosing Party shall retain the burden of establishing its privilege or work product claims. Nothing in this paragraph shall limit the right of any Party to petition the Court for an *in camera* review of the Disclosed Privileged Information.

17. Inadvertent Production or Disclosure of Confidential Material Without Prior

Designation.

- a. Inadvertent or unintentional disclosure, without the required confidentiality designation, of any Document, Testimony, or Information that the Disclosing Party intended to designate as Confidential Material (“Inadvertent Production Without Designation”) shall not be deemed a waiver in whole or in part of the Producing Party’s claim of confidentiality, either as to specific Documents, Testimony, and Information disclosed or as to the same or related subject matter.
- b. In the event that a Designating Party makes such an Inadvertent Production, that Party shall contact the Receiving Party within 30 days of the discovery of the Inadvertent Production, or as promptly as reasonably possible thereafter, and inform the Receiving Party or Parties in writing of the Inadvertent Production and the specific material at issue.
- c. Upon receipt of such notice, the Receiving Party or Parties shall treat the material identified in the notice as confidential until (i) the Parties agree to non-confidential treatment of the subject material, or (ii) the Court, on motion of any Party, issues an order addressing the appropriate treatment of the subject material. Unless the Court orders otherwise, within ten court days of receiving notice of the Inadvertent Production, the Receiving Party shall return or destroy all copies of such Confidential Material and provide a certification of counsel that all such Confidential Material has been returned or destroyed. Each Receiving Party shall notify every person or organization that received copies of or access to the material identified in the notice that such material contains Confidential Material.
- d. As promptly as reasonably possible thereafter, the Disclosing Party shall re-produce

the Confidential Material with the required designation.

18. Remedies.

- a. This Protective Order shall be enforced by the sanctions set forth in Fed. R. Civ. P. 37(b) and any other sanctions as may be available to the presiding judge, including the power to hold parties or other violators of this Protective Order in contempt. All other remedies available to any person injured by a violation of this Protective Order are fully reserved.
- b. Any Party may petition the Court for good cause shown if the Party desires relief from a term or condition of this Protective Order.

AND IT IS SO ORDERED.

A handwritten signature in black ink, reading "Cathy Seibel". The signature is written in a cursive, flowing style.

CATHY SEIBEL
Judge, United States District Court

specifically authorized by the Protective Order, without (1) the express written consent of the party who designated the information as confidential, or (2) order of Court.

I also agree to notify any stenographic, clerical, or technical personnel who are required to assist me of the terms of this Protective Order and its binding effect on them and me.

I understand that I am to retain all documents and materials designated as or containing “Confidential Material” or “Confidential Material—Outside Attorney Eyes Only” in a secure manner, and that all such documents and materials are to remain in my personal custody until the completion of my assigned duties in this matter, whereupon all such documents and materials, including all copies thereof, and any writings prepared by me containing any “Confidential Material” or “Confidential Material—Outside Attorney Eyes Only” are to be destroyed or returned to counsel who provided me with such documents and materials.

Signed

Printed Name

Date